REMARKS

In response to the Office Action of October 3, 2006, claims 1-15 have been canceled without prejudice. Claim 16 is pending.

Claim Rejections Under 35 USC §102

The PTO rejects claim 16 under 35 U.S.C. §102(b) for alleged lack of novelty. Specifically, the PTO asserts that the subject matter of claim 16 is anticipated by an experiment described by Rath et al. (*J. Med. Microbiol.*, January 2001, 50:108-109) in light of a PCR method disclosed by Greisen et al. (*J. Clin. Microbiol.*, 1994, 32:335-351). More specifically, the Examiner asserts that Rath et al. describe a PCR reaction mixture containing DNA that had been phenol-chloroform extracted from bacteria following incubation of the bacteria in gellan gum, resulting in a composition comprising 0.75% gellan gum, water present in the gellan gum, a target nucleic acid, dNTPs, and DNA polymerase.

Applicant respectfully traverses these grounds for rejection. Claim 16 is directed in pertinent part to a composition suitable for use in nucleic acid amplification comprising water, gellan at a concentration above 0.005 wt% based on the weight of water, a DNA polymerase, dNTPs, and a target nucleic acid.

The instant claim is not anticipated for reasons given herein and previously made of record, including the failure of the prior art to disclose the recited composition where there is no showing by the PTO whatsoever, nor any suggestion in the cited documents, that any single composition of Rath et al. or of Greisen et al. contains gellan at a concentration above 0.005 wt% and at the same time also contains a target nucleic acid, dNTPs, a DNA polymerase and water.

In the Office Action, the PTO asserts in essence that in the steps of DNA extraction using phenol-chloroform and DNA precipitation using isopropanol as described by Rath et al., the gellan is not separated from the DNA. As discussed below, this assertion by the PTO is at worst a misreading of Rath et al. and is at best an unfounded conclusion based on a flawed theory of inherent disclosure.

The PTO fails to establish a case of anticipation of the invention over Rath et al. (2001) because the cited publication fails to disclose each and every limitation of the instant

claim. The PTO errs in its reading of Rath et al. as disclosing a PCR reaction mixture that contains 0.75% gellan, because the Office Action ignores the disclosure in Rath et al. at page 108, second column, line 25, that bacterial DNA "was extracted as described above", which refers to steps that include phenol-chloroform extraction, and that specify no temperature above 60°C.

In particular, Rath et al. (2001) fail to teach or in any way suggest the recited composition, which comprises gellan at a concentration above 0.005 wt% based on the weight of water, a DNA polymerase, dNTPs, and a target nucleic acid. At page 2 of the Action, the PTO concedes that the 0.75% gellan gum/bacterial mixture in Rath et al. is *first* subjected to phenol-chloroform extraction and isopropanol precipitation to obtain DNA, which is *subsequently* resuspended in water as a prelude to preparation of a PCR reaction mixture. As such, Applicant submits it is only *after separation of the DNA away from the gellan* that the bacterial target DNA in Rath et al. is mixed with PCR reagents (*e.g.*, DNA polymerase and dNTPs). Accordingly, and contrary to the Examiner's assertion (at page 3, lines 1-3 of the Action) that the PCR reaction mixture in Rath et al. must comprise a composition that contains 0.75% gellan, the cited references are in fact silent with respect to the presence of any gellan in the PCR reaction mixture *per se*. In other words, any composition disclosed by the cited publications as containing gellan does not contain DNA polymerase and dNTPs, and the PTO fails to point to any single composition disclosed by Rath et al. or Greisen et al. in which the presently claimed combination can be found.

Applicant disagrees with the Examiner's specific assertion that the PCR reaction of Rath et al. was performed in 0.75% gellan gum (Examiner's reference to Rath et al., page 108, last paragraph through page 109, first paragraph, and Figure 1). On this point it is noted that all of the bacterial DNA samples described in Rath et al. were subjected to the same phenol-chloroform extraction/isopropanol precipitation procedure (*see e.g.*, page 108, middle of second paragraph of Rath et al.; "Bacterial DNA was extracted *as described above*..." emphasis added). Applicant therefore submits that the Examiner erroneously infers that Rath et al. disclose the presence of gellan in the PCR mixture described therein. From a careful reading of Rath et al., including an appreciation that at page 108, second column, line 25, the disclosure that bacterial DNA "was extracted as described above", a person familiar with the relevant art would clearly

understand that at no point do Rath et al. teach or suggest that a composition is present which comprises gellan at a concentration above 0.005 wt% (and certainly not 0.75% as alleged by the Examiner) along with a DNA polymerase, dNTPs, and a target nucleic acid.

Specifically, Rath et al. treat all of their gellan-containing bacterial samples according to the following steps: (i) homogenization of sample, (ii) addition of proteinase K, (iii) *incubation at 60°C*, (iv) phenol-chloroform extraction, and (v) precipitation of DNA in isopropanol to produce pellet. Applicant notes that the gellan-containing bacterial samples of Rath et al. comprise a block of gellan, in other words, *solidified* gellan. As clearly disclosed in the present application, for example, at page 4, lines 21-28, gellan solidifies into an insoluble gel form that remains stable up to temperatures approaching 100°C. By contrast, Rath et al. and Griesen et al. teach no step performed above 60°C prior to the phenol-chloroform extraction which separates DNA away from contaminants prior to isopropanol precipitation. Thus the PTO fails to provide evidence or reasoning for any conclusion that soluble gellan could be present in the DNA preparations of Rath et al. or Griesen et al.

Moreover, it is well known in the relevant art that in the course of a phenol-chloroform extraction to prepare DNA, the soluble aqueous phase containing DNA is carefully removed away from the organic phase and away from insoluble material accumulating at the aqueous-organic interphase. Insofar as the present application clearly discloses that gellan remains insoluble at 60°C, it follows that insoluble gellan would not co-purify with soluble DNA in the aqueous phase following phenol-chloroform extraction as performed according to well known, art-accepted procedures such as those of Rath et al. As such, when the extracted and precipitated DNA is subsequently resuspended to prepare the PCR reaction mixture, no gellan is present, and the PTO fails to point to any teaching of Rath et al. or of Griesen et al. to suggest otherwise.

In addition, because Rath et al. fail to demonstrate affirmatively that gellan is present in target DNA following phenol-chloroform extraction and isopropanol precipitation, Rath et al. certainly fail to show affirmatively that gellan is present *at a concentration above 0.005 wt% based on the weight of the water* in any PCR reaction that the authors describe.

For reasons given herein, Applicant submits that the Examiner's allegation that gellan is present in the PCR mixture of Rath et al. is technically deficient. Moreover, even

assuming, *arguendo*, that the PTO relies on a theory that gellan is inherently present in the PCR mixture of Rath et al. and Giesen et al., the PTO fails to meet its burden of proving that the cited references disclose each element of the instant claim.

M.P.E.P §2112 provides that:

> In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990) (emphasis in original).

Applicant submits that the burden is on the PTO to supply the requisite basis in fact and/or technical reasoning, where mere conjecture is insufficient to show that the prior art reference anticipates the presently claimed subject matter. As noted herein, Rath et al. provide no basis in fact to support the PTO's allegations, *e.g.*, the authors fail to disclose deliberately adding gellan directly to PCR reactions comprising target DNA. Furthermore, the Examiner has offered no technical reasoning making clear that "the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." (*Continental Can Co. USA v. Monsanto Co.*,948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (M.P.E.P. § 2131.01 (III)).

Rather, in view of the specification teaching of gellan insolubility at temperatures well below 100°C and Applicant's technical argument as discussed herein, in particular the well known practice in the art of collecting the *soluble* aqueous phase in the course of a phenol-chloroform extraction to isolate DNA whilst avoiding any *insoluble* material (*e.g.*, gellan) such as may accumulate at the organic-aqueous interphase in such an extraction, the PTO fails to meet its burden of showing that gellan is necessarily present in the PCR mixture of Rath et al.

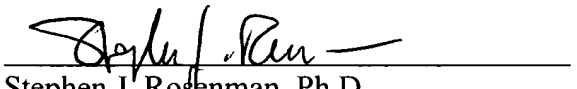
Accordingly, Applicant respectfully submits that the presently claimed subject matter can be distinguished readily over the cited documents, such that reconsideration of the claim and withdrawal of the rejection under §102(b) are respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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